ERA 3000
Dual Chamber Pacing System Analyzer (PSA)

1. 510(K) SUMMARY

JAN 2 7 2003

Name and Address of Sponsor: BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Names:	ERA 3000 Dual Chamber Pacing System Analyzer
Classification:	Class II/III
Classification Name:	External Pacemaker Pulse Generator (21 CFR 870.3600) Pacemaker Electrode Function Tester (21 CFR 870.3630) Pacemaker Generator Function Analyzer (21 CFR 870.3720)
Product Code:	DTA

510(k) Number: K022360

Date Prepared: October 31, 2002

General Description and Predicate Devices:
The ERA 3000 is a portable, dual chamber pacing system analyzer designed to test the electrical performance of the pulse generator and the pacing lead system at the time of pacemaker implantation and during invasive pacemaker troubleshooting or evaluation procedures. It can also operate as a temporary external pulse generator during the above mentioned procedures. The ERA 3000 utilizes a touch-proof configuration to help prevent hazardous connection between patients and electrical power sources.

BIOTRONIK proposes the following Pacing System Analyzer cleared through 510(k) notification as a predicate device for the ERA 3000 Pacing System Analyzer:

- BIOTRONIK's ERA 300 Pacing System Analyzer (#K964190, cleared 07-10-97)

Indications for Use:
The ERA 3000 is intended for use during invasive pacemaker procedures in the following activities:

- **Temporary External Pacing**
  Provides temporary stimulation under DDD, DDI, DOO, VVI, VDD, VOO, AAI, AOO, or ODO modalities during implantable pacemaker procedures or physician evaluations.
- **Lead Threshold Determination**
  Determines in situ lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. Determines the in vivo retrograde conduction time.
- **Pacemaker Function Test**
  Tests and analyzes the in vitro operation of external or implantable pulse generators. Determines the following parameters: pulse amplitude and width, A/V delay, and rate/interval.

Name and Address of Manufacturing Site: BIOTRONIK GmbH & Co. (reg. no. 9610139)
Woermannkehre 1, 12359 Berlin, Germany
Phone: 011-49-30-689-05-304

Name and Address of Contract Manufacturing Site: BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6, 8180 Bülach, Switzerland
Phone: 011-41-1-864-5169

Contact Person and Phone Number: Jon Brumbaugh
Director, Regulatory Affairs
Phone: (888) 345-0374, Fax: (503) 635-9936

2. BIOTRONIK RESPONSE TO FDA QUESTIONS

BIOTRONIK submitted an original 510(k) Premarket Notification application for the ERA 3000 Pacing System Analyzer (#K022360) on July 12, 2002. In correspondence dated October 16, 2002, FDA notified BIOTRONIK of a 30-day hold on the review of the ERA 3000 510(k) application pending receipt of additional information. As a result of this letter, BIOTRONIK submits the following response to each point. To ease FDA's review, the questions from the October 16th letter are shown in bold text with BIOTRONIK's responses shown as non-bold text.

2.1 QUESTION 1: SOFTWARE DEVELOPMENT

1. **FDA has determined that your device is of major level of concern for the purposes of software review. Please provide the following additional information to document your software development process (you may wish to refer to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"):**
    a. **Software Requirements Specification (SRS)**
    b. **Unresolved Anomalies**
    c. **Traceability among requirements, hazards, and Validation and Verification (V&V) tests**

BIOTRONIK uses well established processes and procedures for developing and testing software to be used with all of our medical devices, including implantable products (e.g., implantable pulse generator pacemakers and Implantable Cardioverter Defibrillators (ICDs). These procedures also classify the software used to program and interrogate these devices under a Major Level of Concern (as defined by the referenced FDA guidance document).

2.1.1 Design and Development

BIOTRONIK's Marketing department initially develops general requirement specifications for each BIOTRONIK product. This organization continuously reviews the requirements of the marketplace and identifies the features and specifications that are necessary to satisfy customer's needs. The Marketing organization is primarily concerned with how the device is accepted by clinicians and develops requirements that describe overall functional performance of the pacing system analyzer when working with the implanted device. Depending on the nature of the device, the requirement specifications may be written at a system level or for each component of the system (e.g., pacing system analyzer).

After documentation of general requirement specifications by the Marketing department, the engineering departments develop numerous design specifications. A formal software development protocol and policy have been implemented to assure consistency and conformance to Industry Standards and FDA guidance documents. The project-specific documentation addresses the particular functions required from and by each individual software application including software contained within the devices.

The design specifications that were developed for the software within the ERA 3000 Pacing System Analyzer include:

- General design requirements (Pflichtenheft), PFH-115-014, for implementing the graphical user interface of the ERA 3000 is located in **Appendix 1**.
- General design requirements (Pflichtenheft), PFH-115-041, for the pacemaker portion of the ERA 3000 is located in **Appendix 2**.
- Design specification (DSP 115-038) provides detailed design requirements for the format of data transmissions for the software used in the ERA 3000 and is located in **Appendix 3**.
- Design specification (DSP 115-190) provides detailed design requirements for the software utilized for performing an external pacemaker test and is located in **Appendix 4**.
- Design specification (DSP 115-193) provides detailed design requirements for the user interface and is located in **Appendix 5**.
- Design specification (DSP 115-194) provides detailed design requirements for the pacemaker portion of the ERA 3000 software and is located in **Appendix 6**.

- Design specification (DSP 115-242) provides design requirements for the ERA 3000 software modules and versions and is located in **Appendix 7**.

2.1.2 Risk Management Plan

During the development process, a risk management plan is developed for each device, including the ERA 3000 Pacing System Analyzer. The first step in development of the risk management plan is to determine the appropriate team members for development (if necessary) and review of the individual risk analyses. Because many risks are consistent between groups of products (i.e., pacing system analyzers), some risk analyses are already developed; otherwise, they are developed anew.

After the individual risk analyses are developed and reviewed, the risk management plan is updated to provide information regarding the relationship between numerous risk analysis documentation. At this point, all risks are evaluated and a table is developed to identify the hazard (and its risk analysis), summarize the associated risk reduction measure(s) and specify the design specification (section) and validation test report that address implementation of the risk reduction. The risk management plan then forms the overall risk management strategy utilized in the design and testing of both the software and hardware portions of the system. The Risk Management Plan for the ERA 3000 Pacing System Analyzer, RMP-111-010, is located in **Appendix 8**.

The risk analysis documents generated or utilized for BIOTRONIK's ERA 3000 were previously submitted to FDA as part of the original 510(k) Premarket Notification (K022360, dated July 18, 2002). The applicable risk analyses include the following:

- Risk Analysis (RAN-111-065) provides details of the potential risks and the associated mitigation measures for BIOTRONIK pacing system analyzers, in general. RAN-111-065 was included in Appendix 179 of the original 510(k) Premarket Notification and is also included herein as **Appendix 10**.
- Risk Analysis (RAN-111-043) provides details of the potential risks and the associated mitigation measures for the ERA 3000 Pacing System Analyzer and was included in Appendix 177 of the original 510(k) Premarket Notification.

Associated software specifications and code are written to satisfy internal BIOTRONIK requirements. The design rule documents cover requirements for software functional goals, objectives and hazard analysis. They also describe software developmental aids, including the definition of programming languages, developmental tools, formal software requirements, and documentation and testing. The User Interface Style Guide Document addresses the basic ergonomic design of the user interfaces such as screens and peripheral devices.

Using these documents, the software engineers map an overall software structure, design variables and modules according to coding Standards, write and benchmark code/conduct code walkthroughs, and perform software verification testing. Throughout the software design and development process, software engineers meet and interact with the marketing organization to assure that initial design goals and marketing requirements are met.

After thorough verification and developmental testing during construction of the programming code, the software is presented to the validation department for validation testing. After successful completion of engineering testing during the development stage, validation testing is performed as an independent assessment of the functional performance of the fully-integrated software system. Both Manager and software applications are tested in unison to assure proper communication and functionality. Particular emphasis is placed on safety. Testing, detection and correction of any discovered errors is thoroughly documented with the results in a history file, and a formal report is developed. The testing is comprehensive and is conducted down to module level of the software code.

2.1.3 Description of Software Test and Validation

The Software Engineering Departments are responsible for writing specifications for software development and verification testing. A functional test specification is prepared and software is subsequently tested to determine compliance with these requirements.

During the development and early test phases, the design group at BIOTRONIK performs verification testing. The verification testing includes:

- Dynamic Unit Testing (where appropriate)
- Inspection of Software Modules (where thorough testing is unfeasible)
- Dynamic Integration testing that rigorously tests the efficacy of all parameter values written to the device

As earlier described, the Quality Assurance department independently validates the software once the engineering department has completed verification testing. The validation testing for the ERA 3000, including software, has been completely defined and is detailed in the Validation Test Plan, VPL-111-358, included in **Appendix 9**. This validation plan includes testing of device functionality as well as the risks and associated mitigation measures defined in the risk analysis.

The testing is performed module-by-module, parameter-by-parameter, with a comparison of the anticipated results from the design specifications to the actual results. Any deviation from the expected results are flagged as validation errors and brought back to software engineering for evaluation. Software is considered validated once the entire test and evaluation process is completed.

Upon completion of the validation testing, a validation notification (VAN) is prepared that provides a summary of the test results with the correlating VER numbers for all associated validation results. The product design specification is then revised (DSP, change report section) to indicate the completion of validation and the final configuration of the software.

In response to the detailed questions included in the FDA correspondence, the following sections specify the locations of the requested information.

a. Software Requirement Specification (SRS)

See **Section 2.1.1** above.

b. Unresolved Anomalies

The ERA 3000 software released by BIOTRONIK has all known software anomalies resolved. However, BIOTRONIK does maintain a database with information on any software anomalies or bugs discovered after a version of software is released. This information is available at BIOTRONIK GmbH & Co. in Berlin Germany.

c. Traceability among requirements, hazards, and Validation and Verification (V&V) tests

See **Section 2.1.2** above for device hazard analysis.

See **Section 2.1.2** and **Section 2.1.3** above for traceability analysis, specifically the Risk Management Plan (RMP-111-010) included in **Appendix 8** and the Validation Plan (VPL-111-358) included in **Appendix 9**.

See **Section 2.1.3** and the validation reports included in Section 7.4.1 of the original ERA 3000 510(k) Premarket Notification, submitted on 07-12-02, for a description of validation, verification and testing activities.

d. Additional Information

The following information is also listed as suggested documentation in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" but was not requested by FDA.

1. **Software Description**

   See Section 5.4 of the original ERA 3000 510(k) Premarket Notification, submitted on 07-12-02.

2. **Architecture Design Chart**

   The ERA 3000 software consists of the following modules (sections) that are all treated separately for much of the design and validation phases, but are also tested as a system during final validation testing:

   - IBM-compatible PC with MS-DOS 6.2 (operating system)
   - Manager ("operating system application" used to start and control individual applications)
   - Applications

Figure 1 provides a block diagram of the organization of the ERA 3000 application, operating system and Manager software.

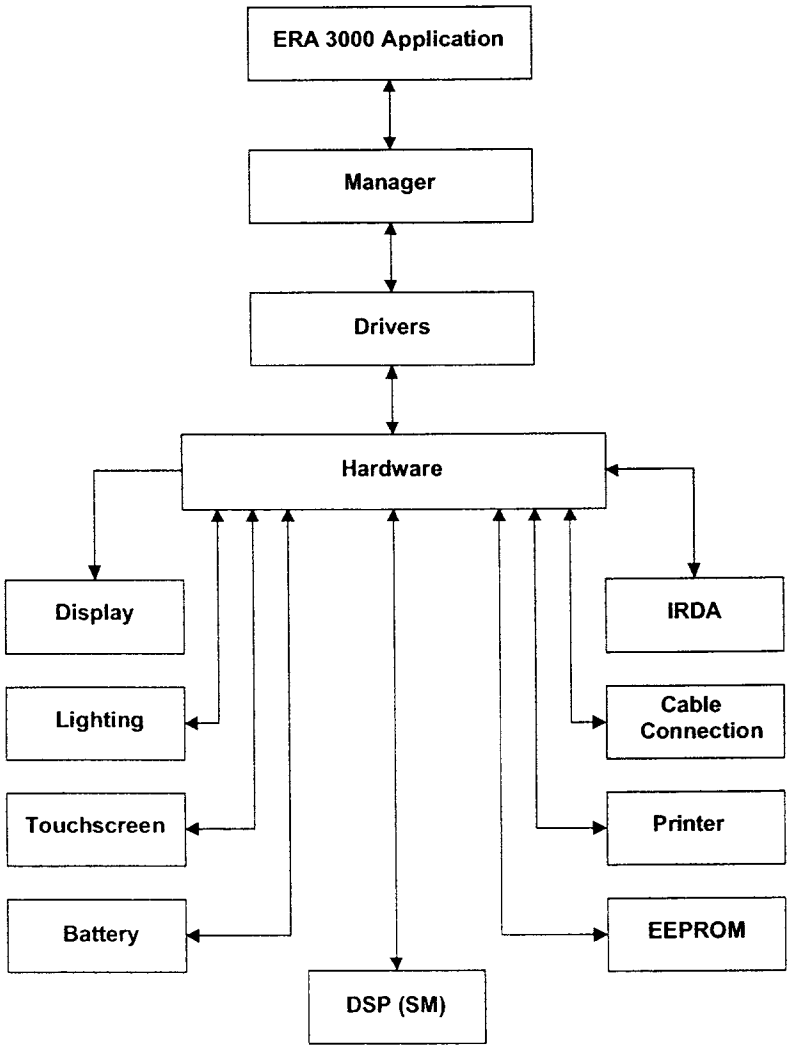

Figure 1: Organization of Software

Refer to **Section 2.1.1** for additional design information. Additional information is available at the manufacturer, BIOTRONIK GmbH & Co.; however, BIOTRONIK believes that the information provided herein and that provided in the 510(k) Premarket Notification (K022360, dated 07-12-02) is sufficient to answer all of FDA's concerns.

3. **Development**

   See previous response to **Question 1**.

4. **A revision history log**

   This information is maintained at BIOTRONIK GmbH & Co. in Berlin Germany. When the software is released for use, the applicable design specification is revised to include the revision history and software configuration information. An example is available in Design Specification (DSP-115-242), located in **Appendix 7**.

5. **The release version number**

   This information for the ERA 3000 software (ERA201.2) is provided in Design Specification (DSP-115-242), located in **Appendix 7**.

2.2 QUESTION 2: RISK ANALYSIS

2. Please define all of the columns (headers) in the Risk Analysis Table for the PSA (Appendix 179).

An error occurred while preparing the Risk Analysis (RAN-111-065) document when the MS Word document was converted into an Adobe Acrobat (PDF) file, which resulted in the landscape pages appearing as portrait pages and subsequent cropping off the table headings. The "MS Word Documents" folder on the submission CD contains an uncorrupt version of the risk analysis. For your convenience, the uncorrupted risk analysis RAN-111-065 (with all the column headers) is provided in **Appendix 10**. The table headings for RAN-111-065 are also shown in the table below. The definitions for the abbreviations shown in the headings are provided in the risk analysis and are also presented in **Table 1**.

Step from PFH	# E	Characteristic / Feature	# G	Hazard / Malfunction	Cause	Consequence for the User / Patient		Risk Evaluation before Measures		Mitigation Measures (u, m, h)	Risk Evaluation after Measures	
							$S_1=S_2$	A_1	R_1 (S_1,A_1)		A_2	R_2 (S_2,A_2)

Table 1: Legend of Header Abbreviations

Abbreviation	Definition
S	Severity Class
A	Likelihood Level
R	Risk Region according to the Risk Chart
PFH	Pflichtenheft (i.e., General design requirements)

2.3 QUESTION 3: DEVICE HISTORY RECORD

3. The device history provided in Appendix 180 is in German. Please provide the device history in English.

The ERA 3000 Device History Record was inadvertently included in the 510(k) Premarket Notification as a German document. The English version of the Device History Record is provided in **Appendix 11**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 7 2003

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
Director, Regulatory Affairs
6024 Jean Road
Lake Oswego, OR 97035

Re: K022360
Trade Name: Pacing System Analyzer
Regulation Number: 21 CFR 870.3720
Regulation Name: Tester, Pacemaker Electrode Function
Regulatory Class: Class III (three)
Product Code: DTA
Dated: October 31, 2002
Received: November 4, 2002

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022360

Device Name: **ERA 3000 Pacing System Analyzer**

Indications For Use:

The ERA 3000 is intended for use during invasive pacemaker procedures in the following activities:

• Temporary External Pacing
Provides temporary stimulation under DDD, DDI, DOO, VVI, VDD, VOO, AAI, AOO, or ODO modalities during implantable pacemaker procedures or physician evaluations.

• Lead Threshold Determination
Determines in situ lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. Determines the in vivo retrograde conduction time.

• Pacemaker Function Test
Tests and analyzes the in vitro operation of external or implantable pulse generators. Determines the following parameters: pulse amplitude and width, A/V delay, and rate/interval.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K022360